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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,127	12/22/2003	Frank J. Bunick	MCP-5022	8480

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
09/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/743,127	BUNICK ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 5-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

Claims 1, 2 and 5-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buxton et al. US 6,428,808 or Dake et al. US 2003/0026872, in view of Mathiowitz et al. US 4,861,627 or Porzio et al. WO 97/13416.

Buxton discloses a liquid oral dosage comprising one or more flavoring vehicles and a medicament (abstract; column 1, lines 44-65; column 5, lines 35-36; and column 6, lines 13-20). The liquid dosage can be in any pharmaceutical formulation such as solution, suspension, emulsion or syrup form (column 2, lines 45-55). Flavoring vehicle comprises an edible solid substrate in the form of a small wafer or thin sheet of water-dispersible or water-soluble non-toxic material, having a thickness of 0.5-2 mm (column 4, lines 33-65). Flavoring vehicle may be in particles form (column 5, lines 21-30). Buxton further discloses the flavoring vehicle is made of known material including starch, cellulose, and polysaccharides (column 4, lines 47-59).

Dake discloses a composition comprising active agent, sweetening agent, and one or more flavoring agents suitable for reconstitution with a liquid, including syrup to form an oral liquid dosage form (abstract; paragraphs 0027-0036, 0110 and 0117; and claims). Flavoring agents include mixture of a variety of well-known forms such as encapsulated flavor agent (paragraphs 0118-0122; and claims).

The cited references Buxton do not teach the claimed encapsulated flavoring vehicle that has a controlled release property.

Mathiowitz teaches a method for the preparation of multilayer microcapsule comprising flavoring agent suitable for controlled release of the flavoring agent (abstract; column 1, lines 9-11; and column 3, lines 55-60).

Porzio teaches a process for preparing a double encapsulated controlled release microspore comprising flavoring agent (abstract; page 22; and claims). Thus, it would have been obvious to one of ordinary skill in the art to modify the teaching of Buxton using the microcapsules in view of the teachings of Mathiowitz and Porzio, because Mathiowitz and Porzio teach microencapsulating flavoring agent is well known in the art, and because Buxton teaches the use of flavoring powder or flavoring granules.

It is noted that the references are silent as to the teaching of flake film, and the film thickness. However, it would have been obvious to one of ordinary skill in the art to, by routine experimentation select flavoring agent in the form of flake film having the thickness that would fall within the claimed range, because Dake teaches using flavoring agents in a variety of well-known, because Buxton teaches a film thickness of 0.5 mm, which is very close to the claimed range (about 0.25 mm), and because Buxton teaches a similar flavoring composition for the same purpose, namely, masking the bitter taste of active agent to obtain a useful pharmaceutical formulation for pediatric and geriatric. Further, the examiner is unable to determine any unexpected result over the particular form of the flavoring agent, for example flake form over particle form. This is because the cited prior arts teach the use of the same flavoring agent useful for the same purpose, such as: 1) flavoring agent suitable for liquid pharmaceutical formulations which masked the taste of bitter active agents to obtain a useful

pharmaceutical formulation for pediatric and geriatric (Buxton); and 2) appealing and uniform taste (Dake at paragraphs 122 and 150)..

Response to Arguments

Applicant's arguments filed 06/27/07 have been fully considered but they are not persuasive.

Applicant argues that the cited references do not teach "particles comprise flaked films that are suspended in the liquid matrix. As discussed on page 11 and Example 2 of the specification, Applicants unexpectedly found that by using flaked film flavorants, such flavorants persisted in the oral cavity after swallowing such liquid pharmaceutical dosage. Specifically, as set forth in Example 2, (i) the customized dosage forms containing flaked films significantly reduced the aftertaste of Children's Tylenol®, (ii) the customized Children's Tylenol® provided a significantly longer lasting flavor experience, (iii) the children were able to distinguish two sequentially-distinct flavors in the customized Children's Tylenol®, and (iv) the flaked films enhanced the overall palatability of Children's Tylenol® suspension, leading to a more likeable taste.

However, it is noted that the cited prior arts teach the same unexpected results desired by the applicant, which include: 1) flavoring agent suitable for liquid pharmaceutical formulations which masked the taste of bitter active agents to obtain a useful pharmaceutical formulation for pediatric and geriatric (Buxton); and 2) appealing and uniform taste (Dake at paragraphs 122 and 150). Accordingly, there is no unexpected result in the claimed "flaked film". Thus, one of ordinary skill in the art

would have been motivated to, by routine experimentation select "flaked film" with the expectation of at least similar results, because the "flaked film" shape is a matter of choice, which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed shape was significant. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SUSAN TRAN
PRIMARY EXAMINER

Art Unit 1615